

**§ 106.1 Biological products; exemption.**

The Administrator may exempt any biological product from one or more of the requirements of this subchapter if he determines that such product will be used by the Department or under the supervision or control of the Department in the prevention, control or eradication of animal diseases in connection with (a) an official USDA program; or (b) an emergency animal disease situation, or (c) a USDA experimental use of the product.

[45 FR 65184, Oct. 2, 1980, as amended at 56 FR 66783, Dec. 26, 1991]

**PART 107—EXEMPTIONS FROM PREPARATION PURSUANT TO AN UNSUSPENDED AND UNREVOKED LICENSE**

Sec.

107.1 Veterinary practitioners and animal owners.

107.2 Products under State license.

AUTHORITY: 21 U.S.C. 151–159; 7 CFR 2.22, 2.80, and 371.4.

**§ 107.1 Veterinary practitioners and animal owners.**

Products prepared as provided in paragraphs (a) and (b) of this section and establishments in which such products are prepared, shall be exempt from preparation pursuant to unsuspended and unrevoked establishment and product licenses. Persons exempt from licensure under this part shipping products which contain live organisms shall provide any information the Administrator may require prior to shipment, or at any other time deemed necessary, in order to assess the products' safety and effect on the environment. The shipment or delivery for shipment anywhere in or from the United States of any exempted product which is worthless, contaminated, dangerous, or harmful is prohibited, and any person shipping such product, or delivering such product for shipment, shall be subject to sanctions under the Act.

(a)(1) Products prepared by a veterinary practitioner (veterinarian) solely for administration to animals in the course of a State licensed professional practice of veterinary medicine by such veterinarian under a veterinarian-

client-patient relationship and establishments in which such products are prepared shall be exempt from licensing under the Act and regulations. Such a relationship is considered to exist when:

(i) The veterinarian has assumed the responsibility for making medical judgments regarding the health of the animal(s) and the need for medical treatment, and the client (owner or other caretaker) has agreed to follow the instructions of the veterinarian; and when

(ii) There is sufficient knowledge of the animal(s) by the veterinarian to initiate at least a general or preliminary diagnosis of the medical condition of the animal(s). This means that the veterinarian has recently seen and is personally acquainted with the keeping and care of the animal(s), and/or by medically appropriate and timely visits to the premises where the animal(s) are kept; and when

(iii) The practicing veterinarian is readily available for followup in case of adverse reactions or failure of the regimen.

(2) Veterinarians preparing products subject to the exemption for products under this section shall maintain and make available for inspection by Animal and Plant Health Inspection Service representatives or other Federal employees designated by the Secretary such records as are necessary to establish that a valid veterinarian-client-patient relationship exists and that there is a valid basis for the exemption under this section.

(b) Products prepared by a person solely for administration to animals owned by that person shall be exempt from the requirement that preparation be pursuant to an unsuspended and unrevoked license.

[52 FR 30131, Aug. 13, 1987, as amended at 56 FR 66783, Dec. 26, 1991]

**§ 107.2 Products under State license.**

(a) The Administrator shall exempt from the requirement of preparation pursuant to an unsuspended and unrevoked USDA establishment and product license, any biological product prepared solely for distribution within the State of production pursuant to a license granted by such State under a

program determined by the Administrator to be consistent with the intent of the Act to prohibit the preparation, sale, barter, exchange, or shipment of worthless, contaminated, dangerous, or harmful biological products.

(b) A request for exemption under this section must be made by the appropriate State authority and shall include information demonstrating that:

(1) The State has the authority to license viruses, serums, toxins, and analogous products and establishments that produce such products; and

(2) The State has the authority to review the purity, safety, potency, and efficacy of such products prior to release to the market; and

(3) The State has the authority to review product test results to assure compliance with applicable standards of purity, safety, and potency prior to release to the market; and

(4) The State has the authority to deal effectively with violations of State law regulating viruses, serums, toxins, and analogous products; and

(5) The State effectively exercises the authority specified in paragraphs (b)(1) through (4) of this section consistent with the intent of the Act prohibiting the preparation, sale, barter, exchange, or shipment of worthless, contaminated, dangerous, or harmful viruses, serums, toxins, or analogous products.

(c) Each product to be exempted and each establishment preparing such product shall be identified by the State and the State shall give written notification to the Administrator of each such product and establishment. The State shall also give written notice to the Administrator of each new license issued and of each license terminated.

(d) In order to determine whether a State exercises its authority with respect to biological products and establishments and whether its laws and regulations are being achieved, the Administrator, in cooperation with proper State authorities, may conduct an on-site evaluation of the State's program which may include inspection of establishments and/or products to be included under the exemptions in this section.

[52 FR 30131, Aug. 13, 1987, as amended at 56 FR 66783, Dec. 26, 1991]

## PART 108—FACILITY REQUIREMENTS FOR LICENSED ESTABLISHMENTS

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108.11 Water quality requirements.

AUTHORITY: 21 U.S.C. 151-159; 7 CFR 2.22, 2.80, and 371.4.

SOURCE: 39 FR 16854, May 10, 1974, unless otherwise noted.

### § 108.1 Applicability.

Unless otherwise authorized by the Administrator, all buildings, appurtenances, and equipment used in the preparation of biological products shall be in compliance with the regulations in this part. Each land area on which such buildings and appurtenances are located shall be identified by an address which shall appear on the establishment license.

[39 FR 16854, May 10, 1974, as amended at 56 FR 66783, Dec. 26, 1991]

### § 108.2 Plot plans, blueprints, and legends required.

Each applicant for an establishment license shall prepare a plot plan showing all buildings for each particular land area, blueprints for each building used in the preparation of biological products and legends containing a brief description of all activities in each room or area.

### § 108.3 Preparation of plot plans.

Plot plans shall show all of the buildings on a particular land area, whether or not they are all used for the preparation and initial shipping of biological products: *Provided*, That, when a great number of buildings are on the same premises, only those surrounding the buildings used for preparation and initial shipping of biological products